

WE CLAIM:

- 1 1. An amorphous form of a salt of esomeprazole.
- 1 2. The amorphous form of a salt of esomeprazole of claim 1, wherein a cation is
2 selected from the group consisting Na, Mg, Li, K, Ca, and N(R)₄, where R is a hydrogen or
3 an alkyl group with 1-4 carbon atoms.
- 1 3. The amorphous form of a salt of esomeprazole of claim 2, wherein the cation
2 comprises Na.
- 1 4. The amorphous form of a salt of esomeprazole of claim 2, wherein the cation
2 comprises Mg.
- 1 5. The amorphous form of a salt of esomeprazole of claim 2, wherein the cation
2 comprises K.
- 1 6. The amorphous form of a salt of esomeprazole of claim 2, wherein the cation
2 comprises Ca.
- 1 7. The amorphous form of a salt of esomeprazole of claim 1, wherein the
2 esomeprazole salt has the X-ray diffraction pattern of Fig. 1.
- 1 8. The amorphous form of a salt of esomeprazole of claim 1, wherein the
2 esomeprazole salt has the IR spectrum of Fig. 2.
- 1 9. A pharmaceutical composition comprising:
2 a therapeutically effective amount of an amorphous form of a salt of esomeprazole;
3 and one or more pharmaceutically acceptable carriers, excipients or diluents.
- 1 10. The pharmaceutical composition of claim 9, wherein a cation is selected from
2 the group consisting of Na, Mg, Li, K, Ca, and N(R)₄, where R is a hydrogen or an alkyl
3 group with 1-4 carbon atoms.
- 1 11. The pharmaceutical composition of claim 10, wherein the cation comprises
2 Na.
- 1 12. The pharmaceutical composition of claim 10, wherein the cation comprises
2 Mg.
- 1 13. The pharmaceutical composition of claim 10, wherein the cation comprises K.

- 1 14. The pharmaceutical composition of claim 10, wherein the cation comprises
2 Ca.
- 1 15. The pharmaceutical composition of claim 10, wherein the esomeprazole salt
2 has the X-ray diffraction pattern of Fig. 1.
- 1 16. The pharmaceutical composition of claim 10, wherein the esomeprazole salt
2 has the IR spectrum of Fig. 2.
- 1 17. A process for the preparation of a salt of the amorphous form of esomeprazole,
2 the process comprising:
3 preparing a solution of a salt of esomeprazole in one or more solvents; and
4 recovering the salt of esomeprazole in the amorphous form from the solution thereof
5 by the removal of the solvent.
- 1 18. The process of claim 17, wherein a cation is selected from the group
2 consisting of Na, Mg, Li, K, Ca, and N(R)₄, where R is a hydrogen or an alkyl group with 1-4
3 carbon atoms.
- 1 19. The process of claim 18, wherein the cation comprises Na.
- 1 20. The process of claim 18, wherein the cation comprises Mg.
- 1 21. The process of claim 18, wherein the cation comprises K.
- 1 22. The process of claim 18, wherein the cation comprises Ca.
- 1 23. The process of claim 17, wherein the solvent comprises one or more of lower
2 alkanol, ketone, ester, chlorinated solvent, acetonitrile or mixtures thereof.
- 1 24. The process of claim 23, wherein the lower alkanol comprises one or more of
2 primary, secondary and tertiary alcohol having from one to six carbon atoms.
- 1 25. The process of claim 23, wherein the lower alkanol comprises one or more of
2 methanol, ethanol, denatured spirit, n-propanol, isopropanol, n-butanol, isobutanol, and t-
3 butanol.
- 1 26. The process of claim 23, wherein the lower alkanol comprises one or more of
2 methanol, ethanol, and denatured spirit.
- 1 27. The process of claim 23, wherein the ketone comprises one or more of
2 acetone, 2-butanone, and 4-methylpentan-2-one.

- 1 28. The process of claim 23, wherein the ester comprises one or more of ethyl
2 acetate and n-butyl acetate.
- 1 29. The process of claim 23, wherein the chlorinated solvent comprises one or
2 more of chloroform and dichloromethane.
- 1 30. The process of claim 17, wherein removing the solvent comprises one or more
2 of distillation, distillation under vacuum, evaporation, spray drying, and freeze drying.
- 1 31. The process of claim 17, wherein the salt of esomeprazole in an amorphous
2 form is recovered from the solution by spray drying.
- 1 32. The process of claim 17, wherein the salt of esomeprazole in an amorphous
2 form is recovered from the solution by freeze-drying.
- 1 33. The process of claim 17, further comprising additional drying of the product
2 obtained.
- 1 34. The process of claim 17, further comprising forming the product obtained into
2 a finished dosage form.
- 1 35. The process of claim 17, further comprises adding one or both of an organic
2 amine and ammonia to the solution.
- 1 36. The process of claim 36, wherein the organic amine and/or ammonia is added
2 to the solution prior to removal of the solvent.
- 1 37. The process of claim 17, wherein the amorphous esomeprazole salt obtained
2 has the X-ray diffraction pattern of Fig. 1.
- 1 38. The process of claim 17, wherein the amorphous esomeprazole salt obtained
2 has the IR spectrum of Fig. 2.